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09/869,208	10/12/2001	Leendert Koenderman	7238/0J504	9804

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EXAMINER

BELYAVSKIY, MICHAIL A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/869,208

Applicant(s)

KOENDERMAN ET AL.

Examiner

Michail A Belyavskyi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 5-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4 and 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 11/06/03 is acknowledged.

Claims 1-22 are pending.

Claims 1, 5-13 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 2-4 and 14-22 are under consideration in the instant application.

In view of the amendment, filed 11/06/03 the following rejections remain

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-4 and 14-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a phagocyte-recognizing agent, wherein phagocyte-recognizing agent is a bacteriophage clones isolated from strains A17 and A24 with accession numbers CBS 101481 and 101482 and a pharmaceutical composition comprising said agent does not reasonably provide enablement for *any* phagocyte-recognizing agent wherein *any* phagocyte-recognizing agent recognizes the agent that is recognized by at least one bacteriophage as can be isolated from the strain having accession number CBS 101481 and 101482 (clone A17 and A27 respectively). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons set forth in the previous Office Action, mailed 05/05/03.

Applicant's arguments, filed 11/06/03 have been fully considered, but have not been found convincing.

Applicant asserts that: (i) the specification describes the preparation and screening of a bacteriophage library and the successful identification of two a bacteriophage clones isolated from strains A17 and A24. Such screening or competitive binding assays could be conducted in a similar manner screening for agents that compete with either one of the bacteriophages; (ii) while some experimentation may be necessary to enable the invention no undue experimentation

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is required for one skill in the art as it involves routine screening and binding assays exemplified in the present disclosure.

Contrary to Applicant's assertion, the instant fact pattern fails to indicate that representative number of structurally related compounds, i.e. *any* phagocyte-recognizing agent wherein *any* phagocyte-recognizing agent recognizes the agent that is recognized by at least one bacteriophage isolated from clone A17 and A27 is disclosed, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claims and consequently would not know how to make them. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product.

As was stated in the Previous Office Action, there is insufficient guidance and direction as to how to make *any* phagocyte-recognizing agent wherein *any* phagocyte-recognizing agent recognizes the agent that is recognized by at least one bacteriophage isolated from strains A17 and A27. Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) that distinctly identifies such "phagocyte-recognizing agent" other than specific bacteriophage isolated from strains A17 and A27 having accession number CBS 101481 and 101482. While "*any* phagocyte-recognizing agent" may have some notion of the activity of bacteriophage isolated from strains A17 and A27, claiming biochemical molecules by such properties fails to provide sufficient guidance and direction as to how the skilled artisan can make and use such "phagocyte-recognizing agent", commensurate in scope with the claimed invention. It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different pharmacological activities. Applicant has not enabled structurally related and unrelated compounds comprising *any* phagocyte-recognizing agent recognizes the agent that is recognized by at least one bacteriophage isolated from strains A17 and A27 would be expected to have greater differences in their activities. There is insufficient direction or objective evidence as to how to make and to how to use any agent which recognizes the agent that is recognized by at least one bacteriophage isolated from strains A17 and A27 (e.g. desired/intended effect of the claimed limitations). Moreover, the present specification failed to provide any biochemical and structural characteristics of the 'agent', or "epitope" that is recognized by specific bacteriophage isolated from strains A17 and A27 having accession number CBS 101481 and 101482. The common attributes of such "agent" or 'epitope' are not described. Detailed information regarding the specific epitopes recognized by the instant specific bacteriophage isolated from strains A17 and A27 having accession number CBS 101481 and 101482 is lacking. Therefore, predicting which "phagocyte-recognizing agent" outside of "bacteriophage isolated from strains A17 and A27 having accession number CBS 101481 and 101482" is well outside the realm of routine experimentation. A skilled artisan would require guidance, such as the structure and biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) of the agent recognized by bacteriophage isolated from strains A17 and A27 successfully used in the instant invention in order to provide enablement for *any* phagocyte-recognizing agent wherein *any* phagocyte-recognizing agent recognizes the agent that is recognized by at least one bacteriophage as can be isolated from the strain having accession number CBS 101481 and 101482 in a manner reasonably commensurate with the scope of the

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claims. Thus, it would require undue experimentation of one skilled in the art to practice the claimed invention.

The scope of the claimed *any* phagocyte-recognizing agent wherein *any* phagocyte-recognizing agent recognizes the agent that is recognized by at least one bacteriophage as can be isolated from the starain having accession number CBS 101481 and 101482 is not commensurate with the enablement provided by the disclosure of specific bacteriophage isolated from the starain having accession number CBS 101481 and 101482. with regard to the extremely large number of amino acid sequences broadly encompassed by the claimed invention. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's or peptide's amino acid sequence, and, in turn, nucleic acid sequence and still retain similar biological activity or structural specificity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a limited number of proteins and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex and well outside the realm of routine experimentation.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed *any* phagocyte-recognizing agent recognizes the agent that is recognized by at least one bacteriophage as can be isolated from the starain having accession number CBS 101481 and 101482 in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

4. Claims 2-4 and 14-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the same reasons set forth in the previous Office Action, mailed 05/05/03.

Applicant's arguments, filed 11/06/03 have been fully considered, but have not been found convincing.

Applicant asserted that the skill artisan would readily recognize that being in possession of two specific specific ligand sequences means that other agents having the same binding specificity are available by routine methods, including high-throughput screening methods.

Contrary to Applicant's assertion, a description of what a material does rather than of what it is, usually does not suffice. The patent does not more than describe the desired function of the

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compound called for and contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work. Inadequate written description that merely identifies a plan to accomplish an intended result “is an attempt to preempt the future before it has arrived” *Fiers v. Revel*, 984 F.2d 1164, 1171 9Fed.Cir. 1993). A description of *any* agent by functional language, i.e. having the same binding specificity as two references bacteriophage clones isolated from strains A17 and A24 in the absence of a structure is not considered sufficient to show possession of the claimed invention. It is only a definition of a useful result rather than a definition of what achieves that result. Many species may achieve that result. The definition requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 22 USPQ 369, 372-73 (Fed. Cir. 1984) affirming the rejection because the specification does “little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what the material consists of (e.g. structural feature), is not a description of that material.

Applicant is in possession of : phagocyte-recognizing agent , wherein phagocyte-recognizing agent is a bacteriophage clones isolated from strains A17 and A24 with accession numbers CBS 101481 and 101482.

Applicant is not in possession of : *any* phagocyte-recognizing agent recognizes the agent that is recognized by at least one bacteriophage as can be isolated from the starain having accession number CBS 101481 and 101482.

A description of a genus of phagocyte-recognizing agent may be achieved by means of a recitation of a representative number of agents, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 “Written Description” Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

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The following new ground of rejection is necessitated by the amendment filed 11/06/03.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 14-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a New Matter rejection.

Any phagocyte-recognizing agent which is capable of competitive binding or inhibition of a bacteriophages from strain CBS101481 or CBS101482 to a phagocyte or a GM-CSF primed granulocyte claimed in claims 14, 18, 19 and 22; any phagocyte-recognizing agent comprising an antigen-binding part of an antibody, claimed in claims 15, 20 and 22; and any phagocyte-recognizing agent comprising the antigen-specific sequence of a bacteriophage from strain CBS101481 or CBS101482, claimed in claim 17 represent a departure from the specification and the claims as originally filed.

The passages pointed by the applicant do not provide a clear support for : (i) Any phagocyte-recognizing agent which is capable of competitive binding or inhibition of a bacteriophages from strain CBS101481 or CBS101482 to a phagocyte or a GM-CSF primed granulocyte claimed in claims 14, 18, 19 and 22; (ii) any phagocyte-recognizing agent comprising an antigen-binding part of an antibody, claimed in claims 15, 20 and 22; (iii) any phagocyte-recognizing agent comprising the antigen-specific sequence of a bacteriophage from strain CBS101481 or CBS101482, claimed in claim 17.

The specification and the claims as originally filed only support: (i) an agent capable of competing with a bacteriophages from strain CBS101481 or CBS101482 (page 3, lines 7-11); (ii) ScFv-fragments and humanized antibody with the antigen-recognizing sequences of bacteriophage A17 (page 5, line 30-39 and page 10, lines 1-13).

7. No claim is allowed

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is 703/872-9306.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
January 23, 2004


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